7 510(k) Summary

JUN 1 3 2013

The following 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

Device Name and Classification

Device Trade Name:	Pipeline Total Hip System – Line Extension
Device Common Name:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI (hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented) MEH (prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate)
Advisory Panel:	Orthopedic

Address and Registration

Submitter's Name:	Pipeline Orthopedics
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	April 30, 2013
Establishment Registration Number:	3009701876

Purpose of Submission

This Special 510(k) addresses an administrative line extension to the Pipeline Total Hip System (510(k) #K112802), and introduces hip system components that have already been determined substantially equivalent by FDA in 510(k) #K122158 for the designated indications for use under the name of the holding company's other subsidiary.

Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject HA-coated Acetabular Shells, Biolox® *delta* Ceramic Femoral Heads, 40mm CoCr Femoral Heads, and corresponding 40mm inner diameter Highly Crosslinked Vitamin E UHMWPE Liners submitted in this 510(k) under the name of Pipeline Biomedical Holdings' subsidiary, Pipeline Orthopedics, are identical, and therefore substantially equivalent to, the same devices cleared under the name of Pipeline Biomedical Holdings' subsidiary, Pipeline Biomedical Products, in predicate 510(k) number K122158.

Device Description

This 510(k) addresses the addition of the following components (already cleared under 510(k) #K122158) to the Pipeline Total Hip System:

- HA-coated Acetabular Shells feature a thin HA coating applied over the porous structured (PST) shells in a range of sizes,
- Biolox® *delta* Ceramic Femoral Heads available in a range of diameters and extension options,
- 40mm CoCr Femoral Heads, and
- 40mm inner diameter Highly Crosslinked Vitamin E UHMWPE Acetabular Liners.

These components are compatible with the total hip system determined substantially equivalent as the Pipeline Total Hip System in 510(k) #K112802 and as the PBP Total Hip System in 510(k) #K122158.

Intended Use

The Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Tapered Hip Stem and PST™ Acetabular Shell are intended for cementless or cemented fixation. The porous structured (PST™) surface provides biological fixation when used in a cementless application.

The Pipeline Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Comparison of Technological Characteristics

The HA-coated Acetabular Shells, Biolox® *delta* Ceramic Femoral Heads, 40mm CoCr Femoral Heads, and 40mm inner diameter Highly Crosslinked Vitamin E UHMWPE Acetabular Liners are identical to the same components determined substantially equivalent in predicate 510(k) #K122158 in all respects except for the Pipeline Biomedical Holdings subsidiary name assigned to the 510(k). There is no difference in intended use, materials, design features, component sizing, or manufacturing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2013

Pipeline Orthopedics
% M Squared Associates, Incorporated
Ms. Terry Sheridan Powell
Senior Project Manager
901 King Street, Suite 101
Alexandria, Virginia 22314

Re: K131237
Trade/Device Name: Pipeline Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, OQG, OQH, LZO, OQI, MEH
Dated: May 14, 2013
Received: May 15, 2013

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6 Indication for Use Statement

510(k) Number (if known): K 131237 to be assigned

The Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Tapered Hip Stem and PST™ Acetabular Shell are intended for cementless or cemented fixation. The porous structured (PST™) surface provides biological fixation when used in a cementless application.

The Pipeline Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

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